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O'Connor

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(54) **ELECTRODE INSERTION TOOLS, LEAD ASSEMBLIES, KITS AND METHODS FOR PLACEMENT OF CARDIAC DEVICE ELECTRODES**

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(52) **U.S. Cl.**
CPC **A61N 1/0587** (2013.01); **A61N 1/05** (2013.01)

(58) **Field of Classification Search**
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USPC 607/40, 119
See application file for complete search history.

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Primary Examiner — Christopher D Koharski

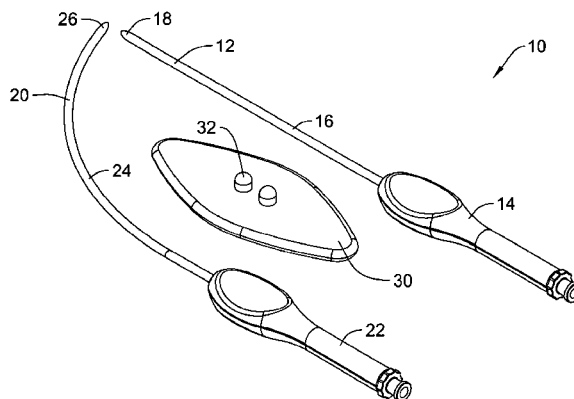
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(57) **ABSTRACT**

Insertion tools, lead assemblies, kits, and methods for placement of cardiac device electrodes. In some embodiments, an insertion tool having a proximal end and a distal, dissecting end includes a structure configured to receive or engage a structure on a lead assembly. Some embodiments include a lead assembly having an end including a structure configured for engaging the distal end of an associated insertion tool. Some embodiments include kits or systems including both an insertion tool and a lead assembly, each having a structure for engaging the other. In these embodiments, the engaging structures may take several forms including threads, small posts, circular or semi-circular receiving members, and/or a slot. Some embodiments also include methods for placement of cardiac device electrodes with the assistance of an associated insertion tool, wherein the cardiac device electrodes are associated with a lead assembly having an end configured to engage a distal, dissecting portion of an associated insertion tool.

9 Claims, 16 Drawing Sheets



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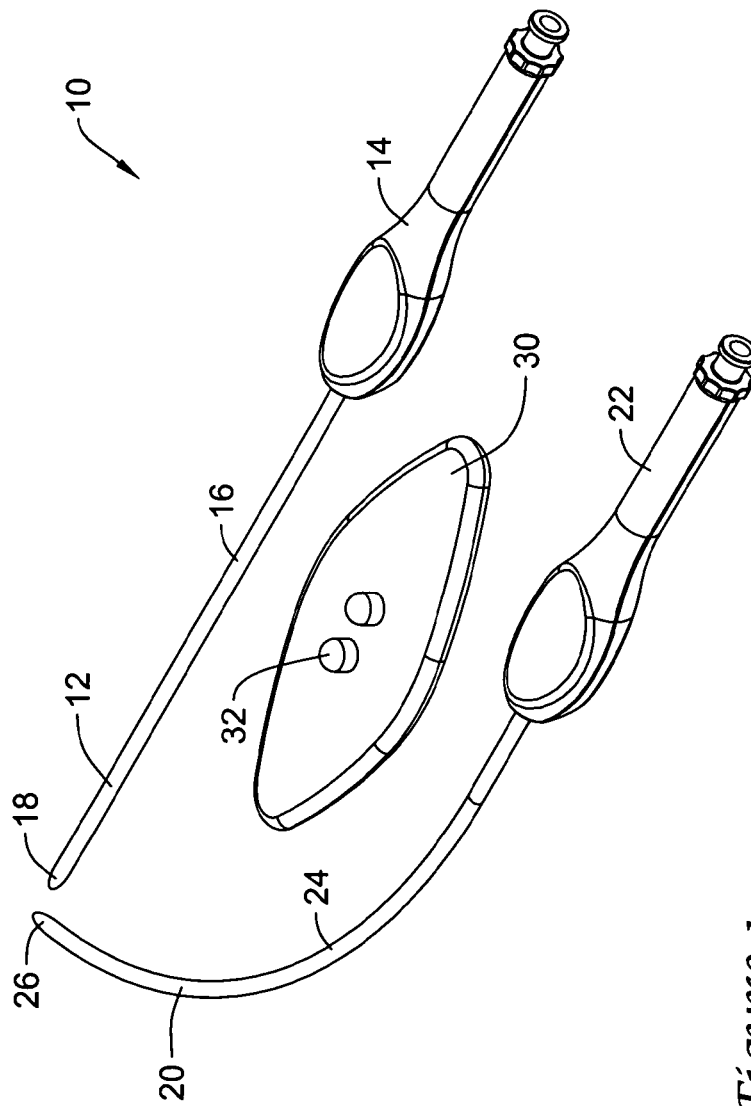


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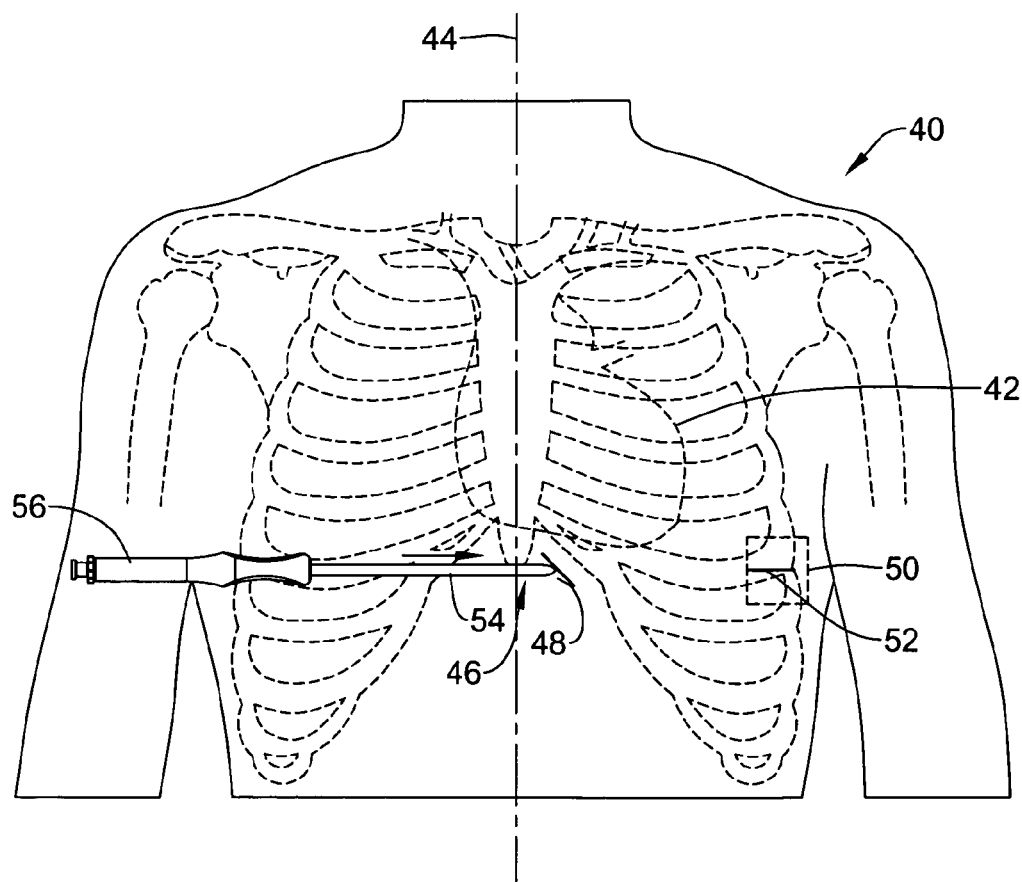


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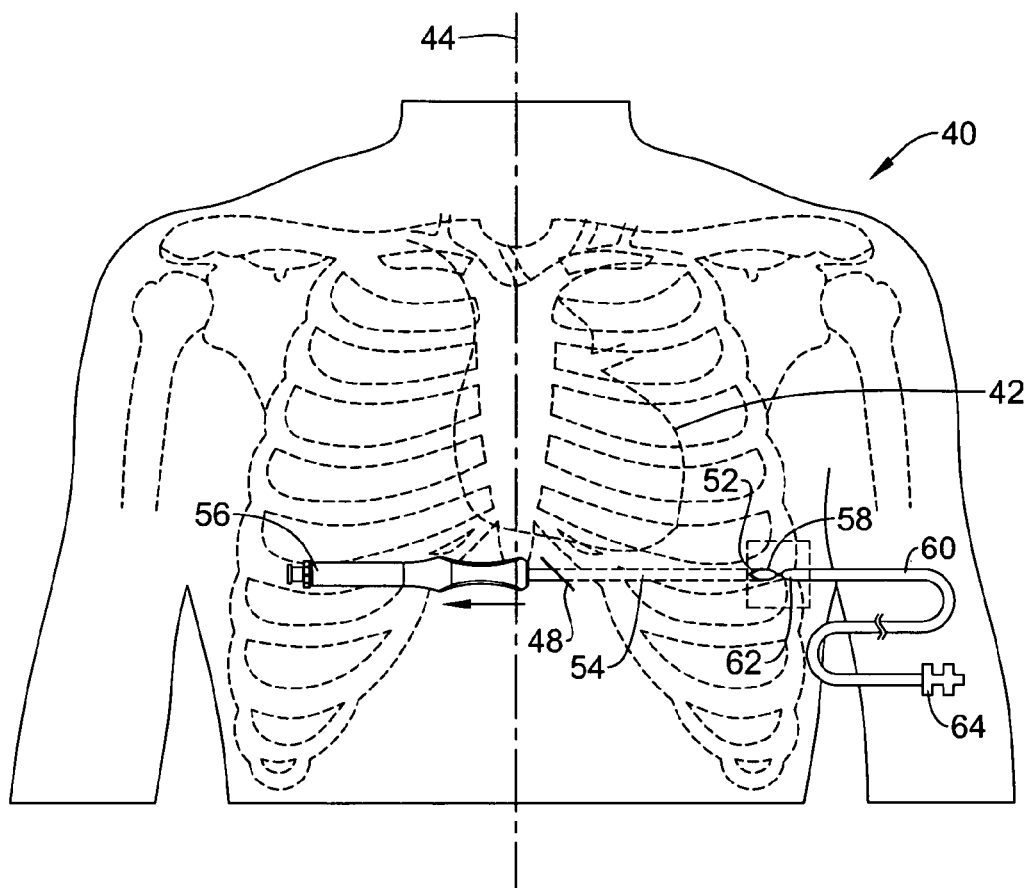


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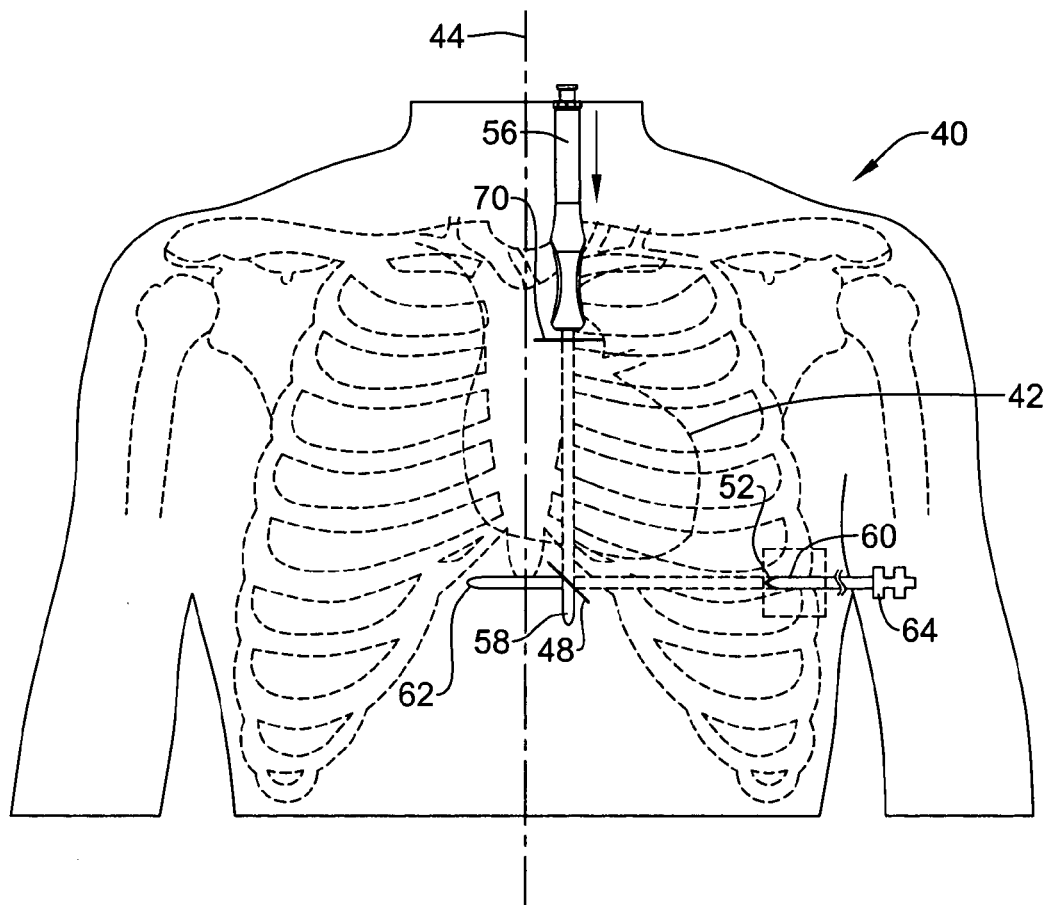


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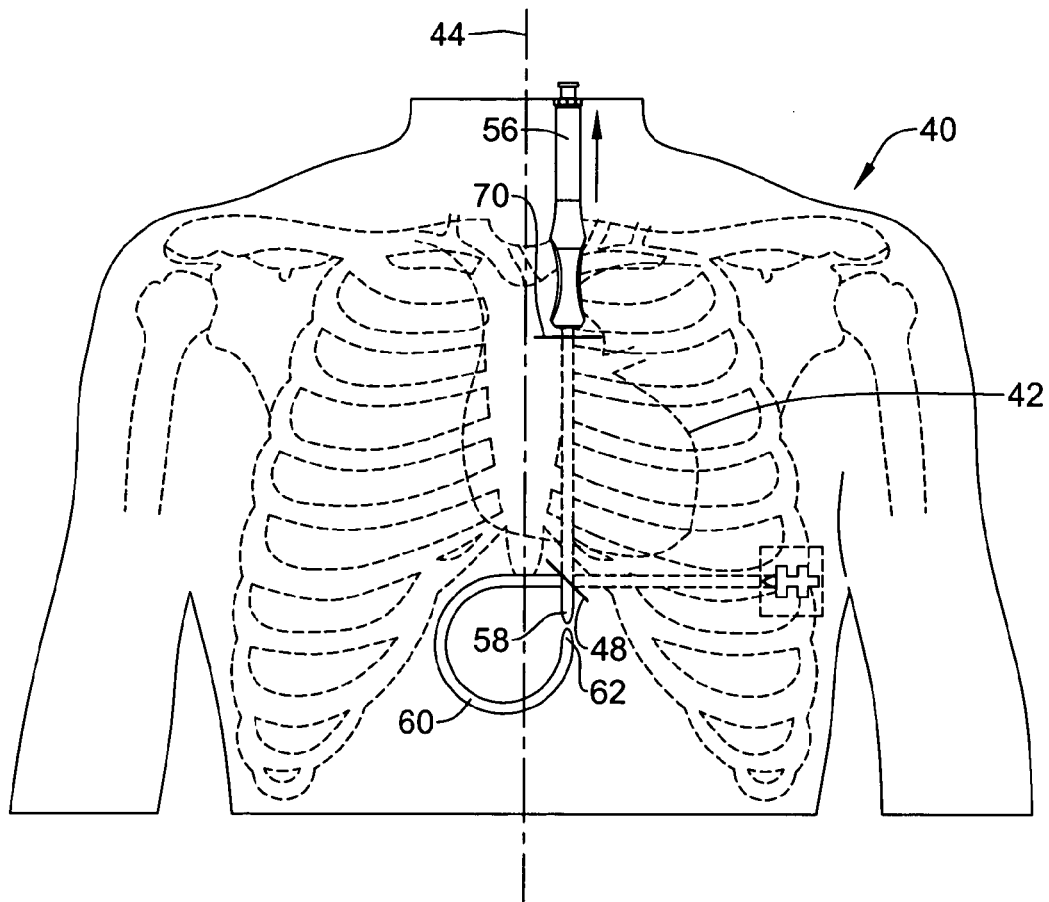


Figure 2D

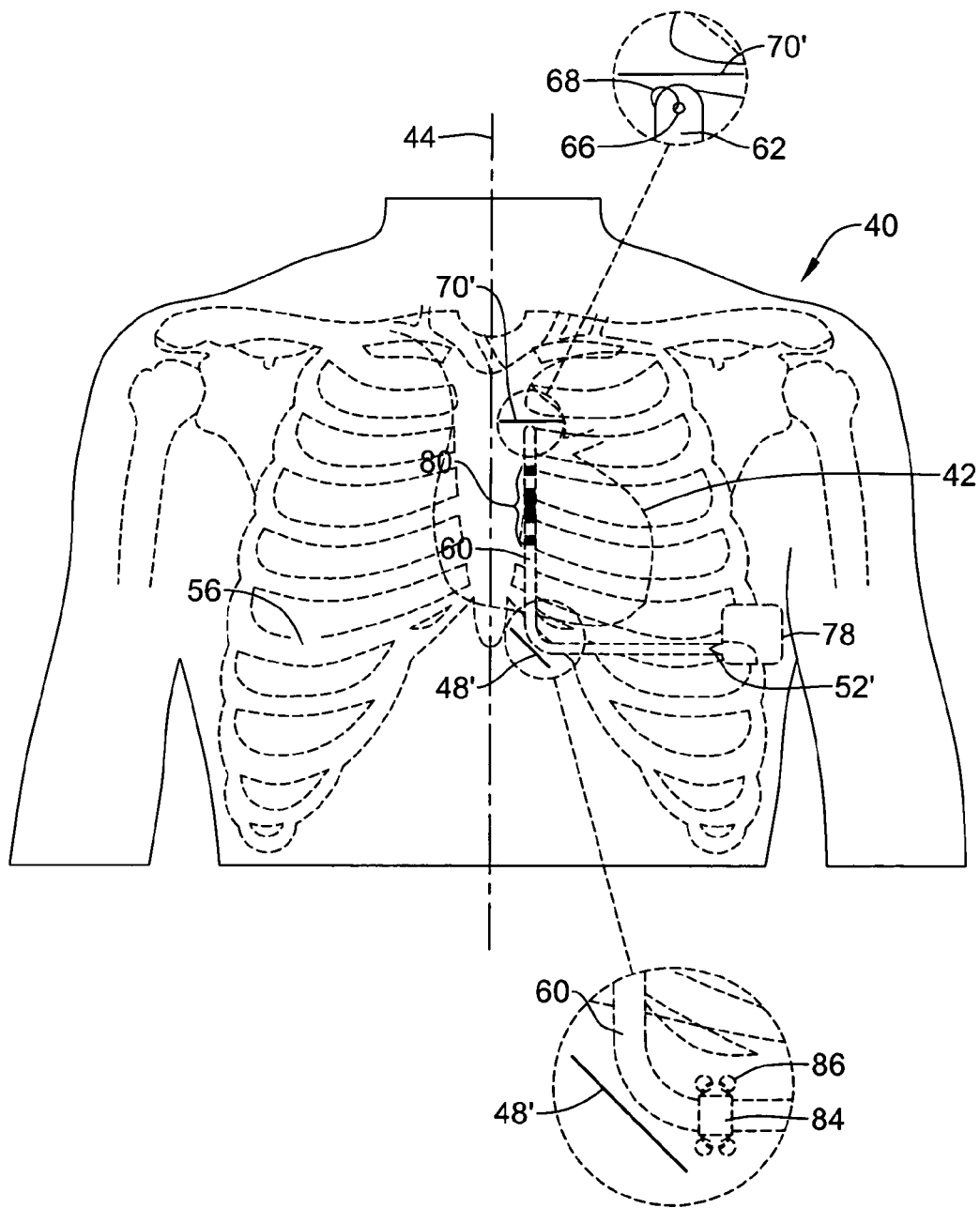


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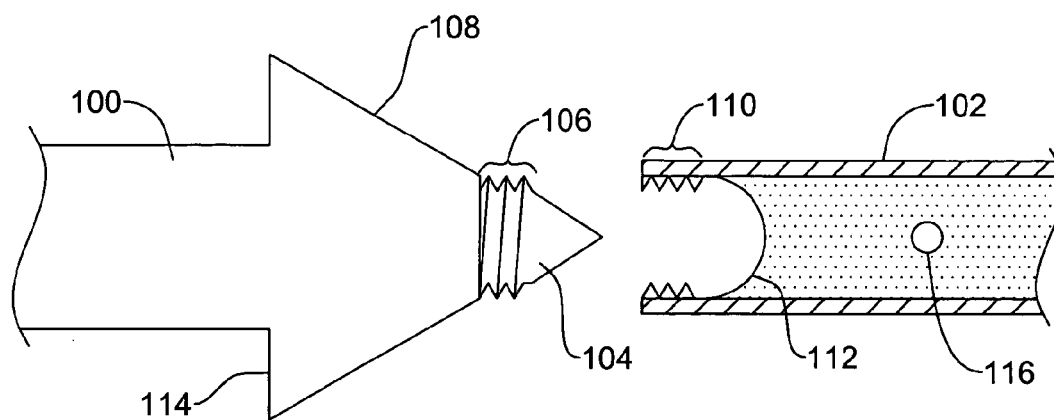


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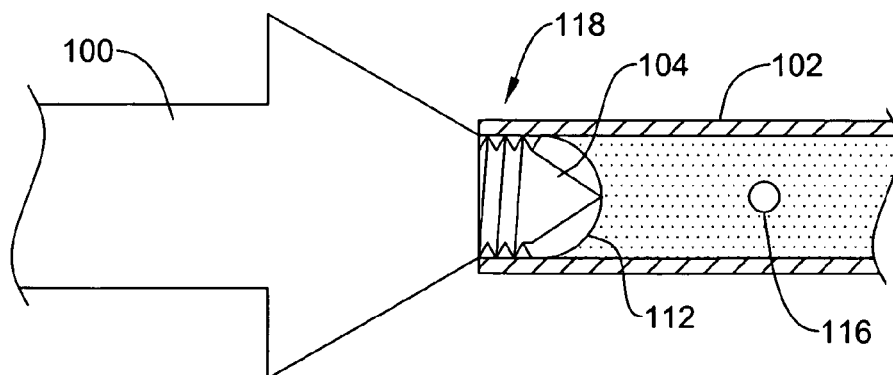


Figure 3B

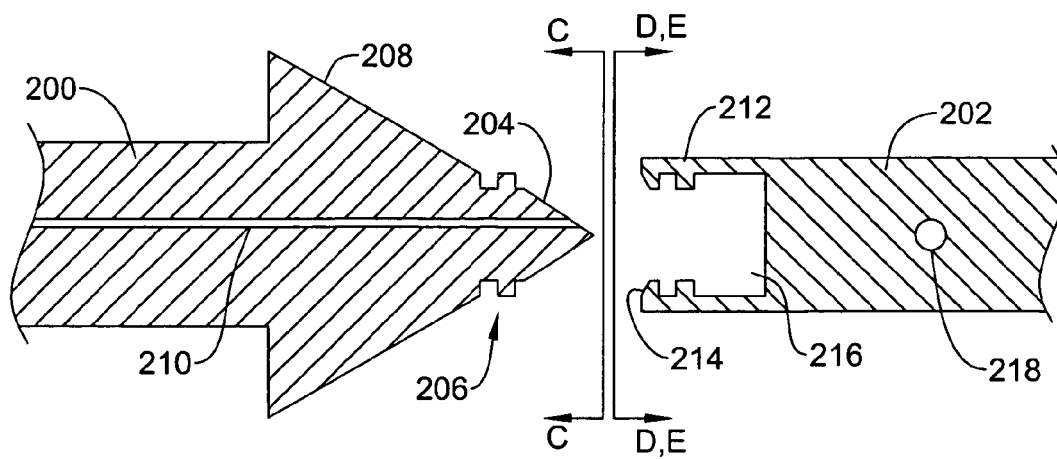


Figure 4A

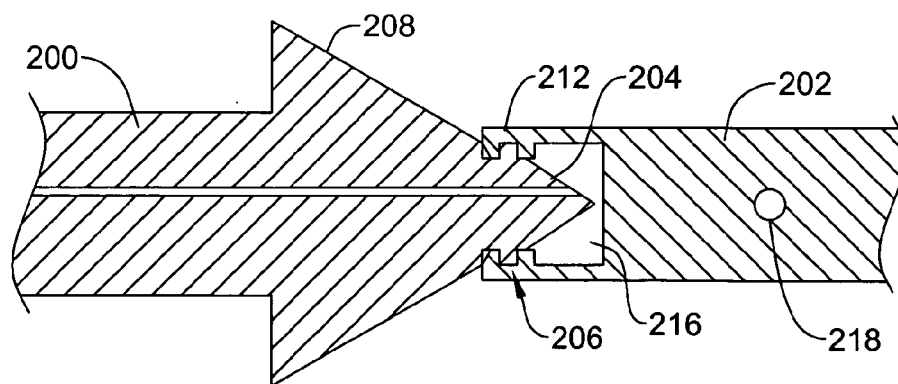


Figure 4B

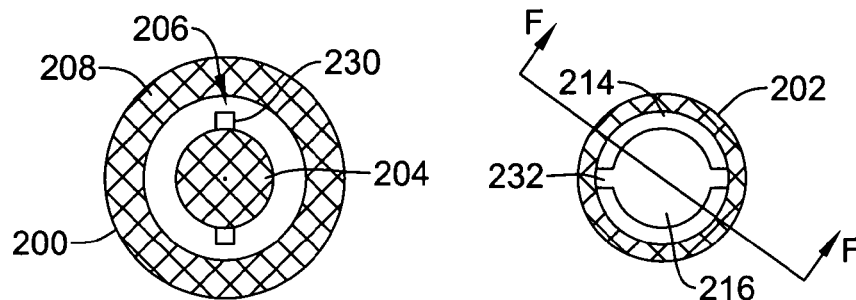


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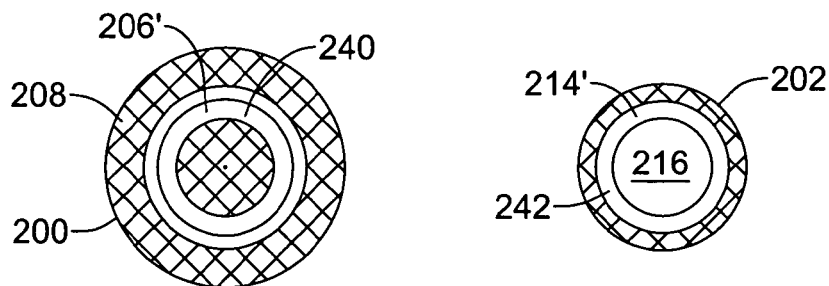


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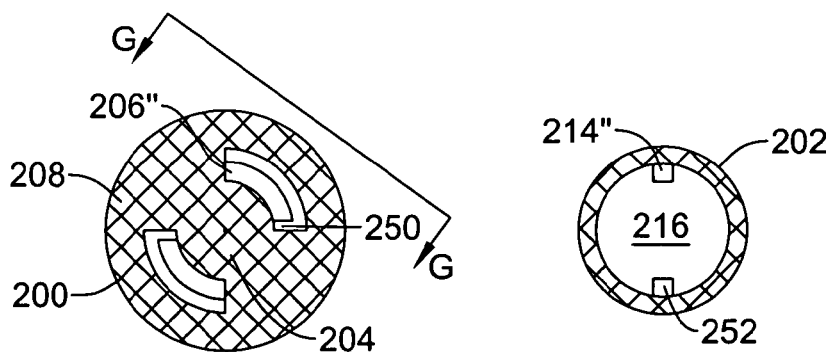


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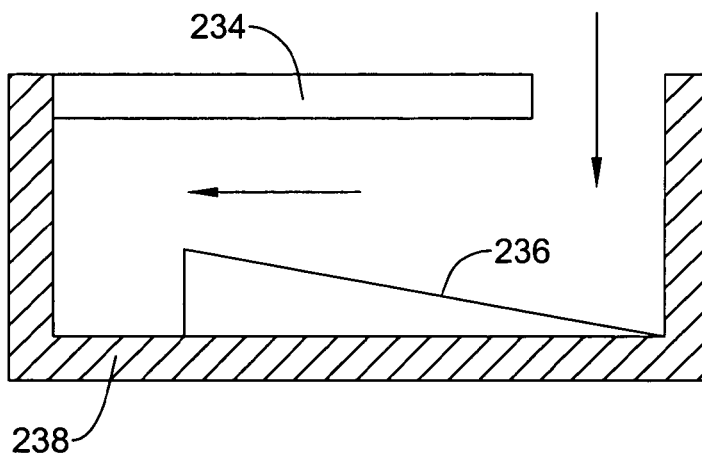


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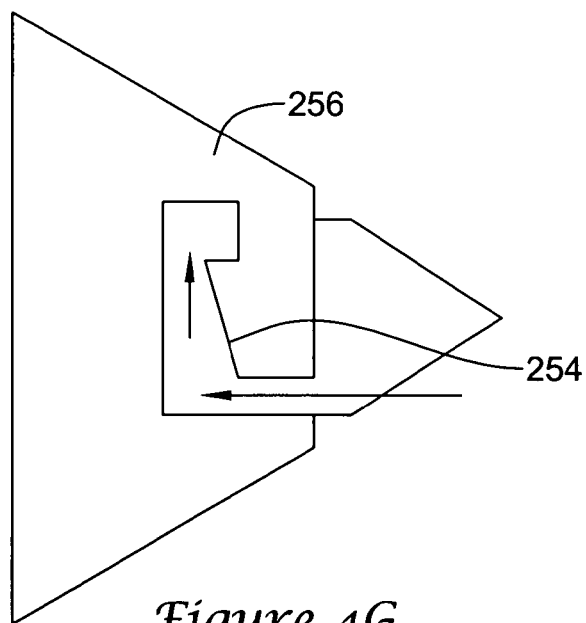


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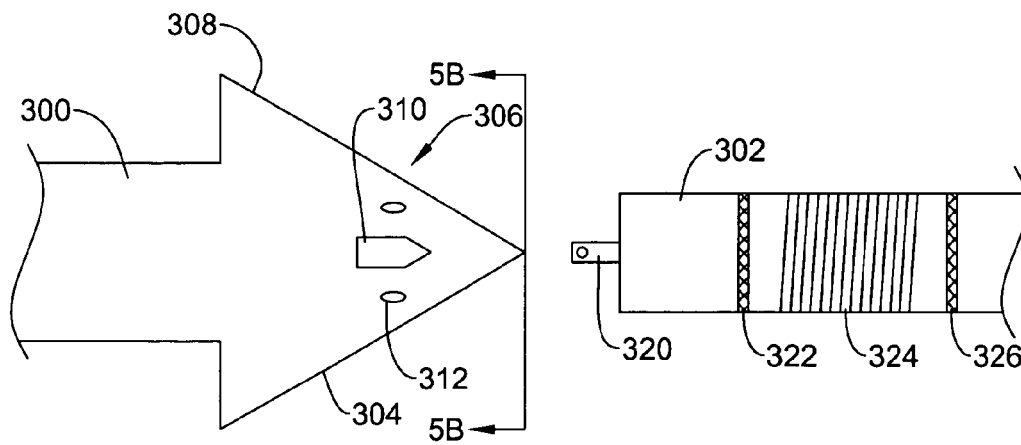


Figure 5A

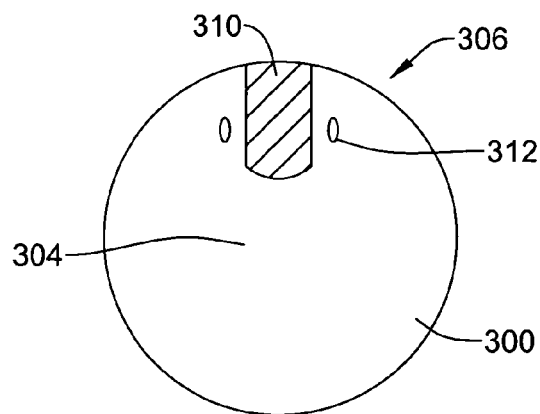


Figure 5B

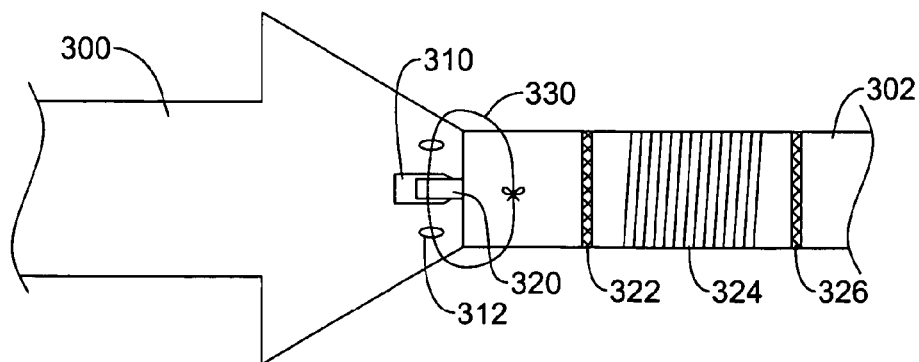


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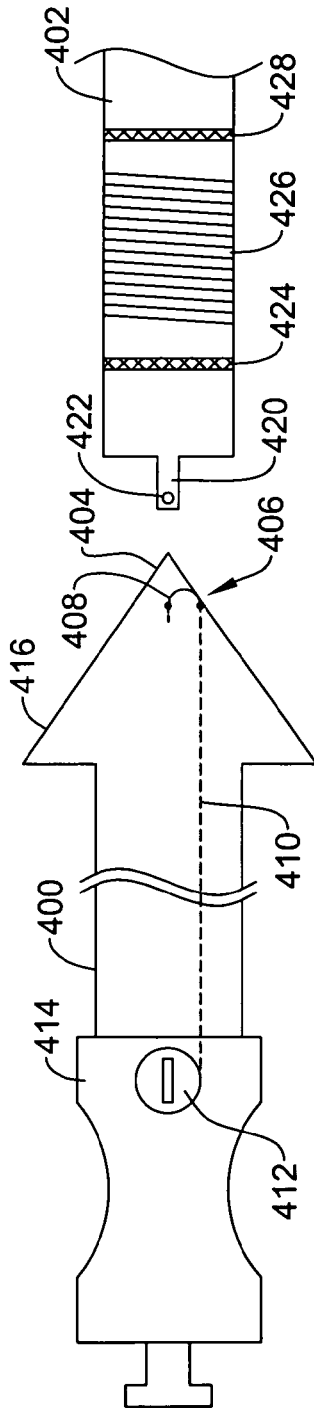


Figure 6A

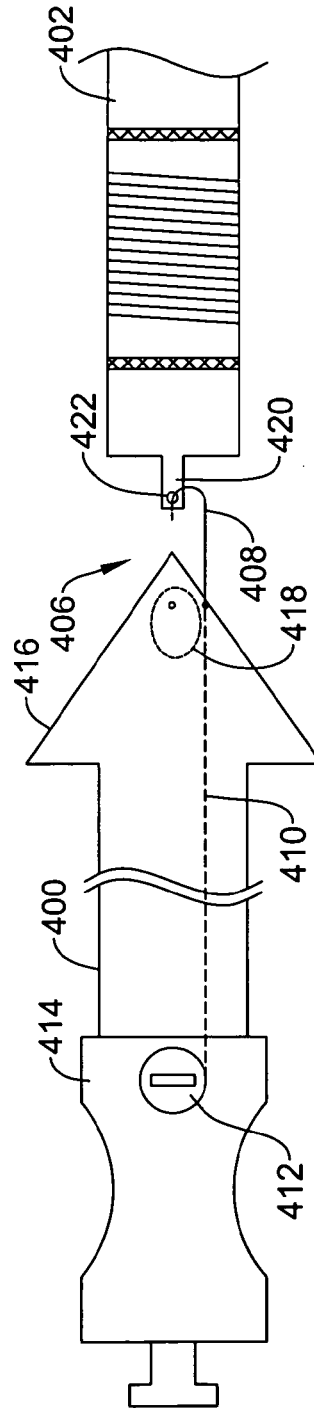
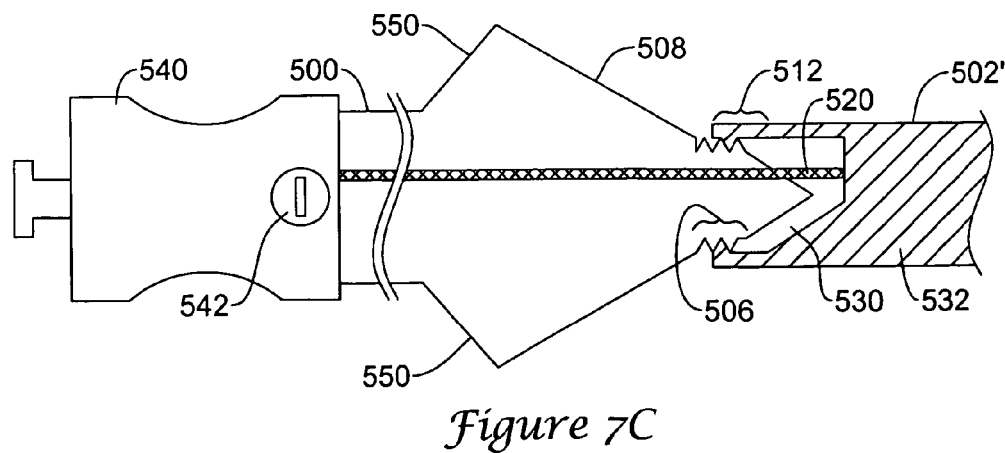
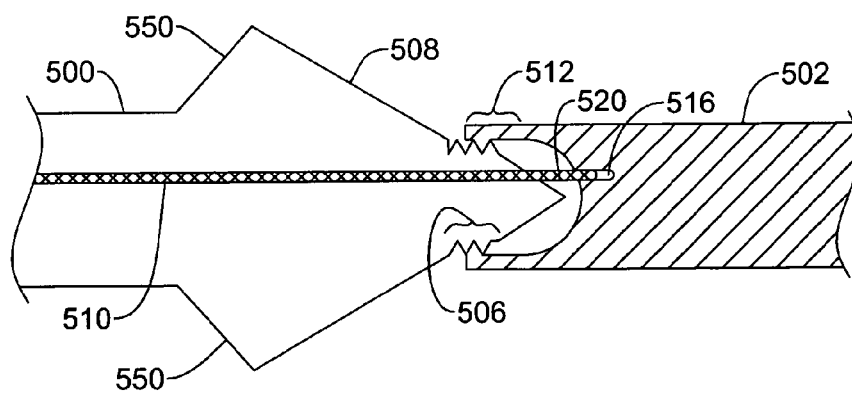
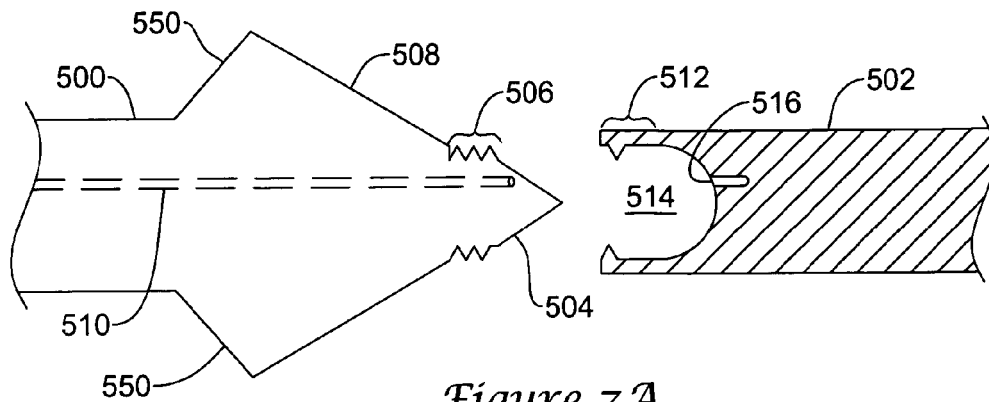


Figure 6B



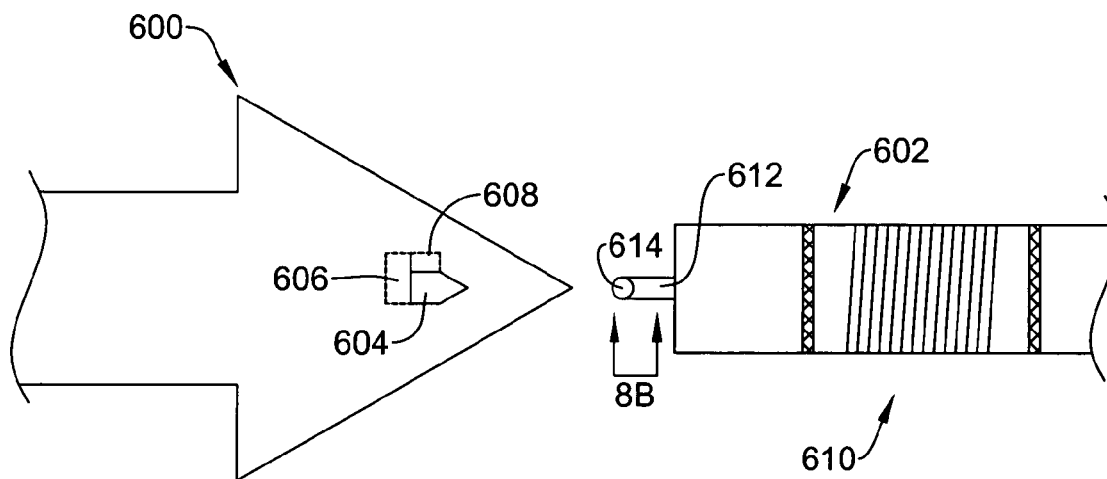


Figure 8A

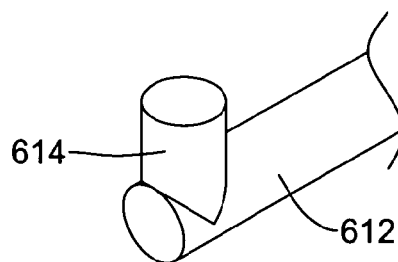


Figure 8B

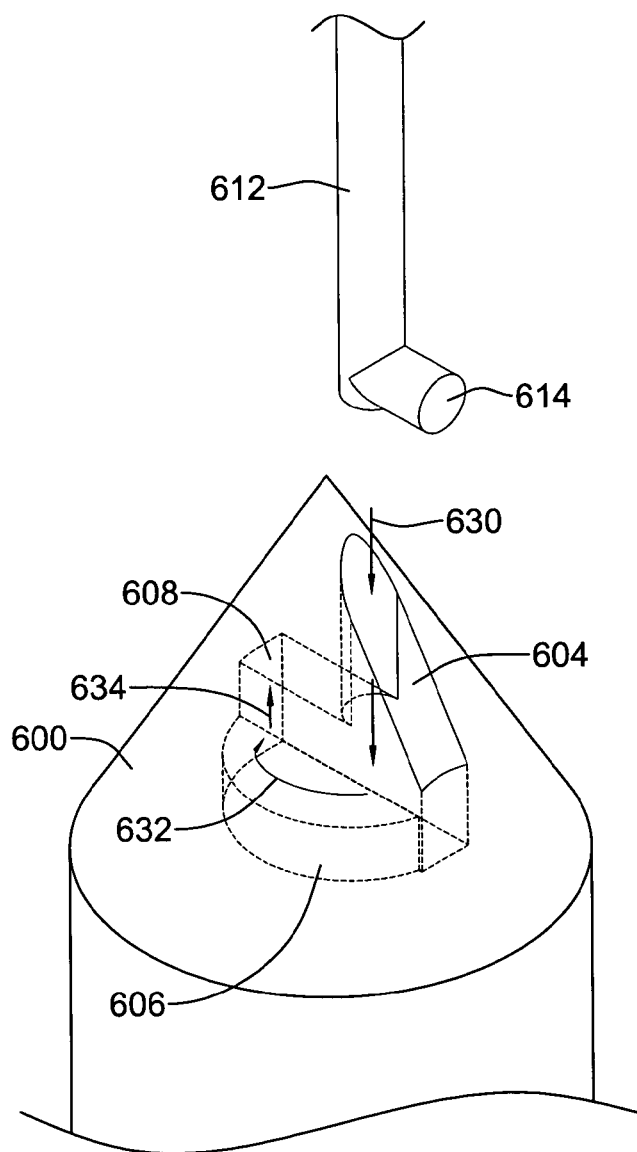


Figure 8C

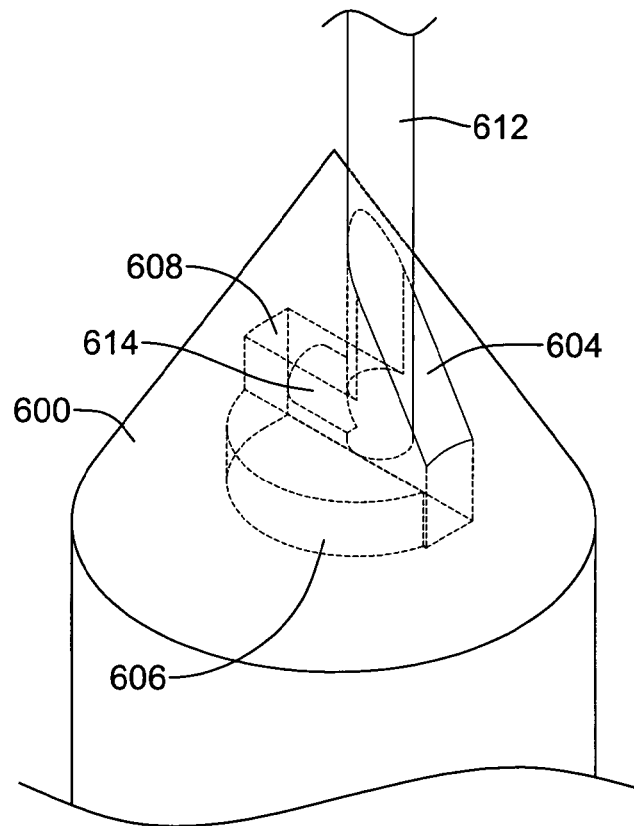


Figure 8D

1

ELECTRODE INSERTION TOOLS, LEAD ASSEMBLIES, KITS AND METHODS FOR PLACEMENT OF CARDIAC DEVICE ELECTRODES

CROSS REFERENCE TO RELATED APPLICATIONS

This Application is a divisional of U.S. patent application Ser. No. 11/497,203, filed on Aug. 1, 2006, now issued as U.S. Pat. No. 8,718,793, the benefit of priority of which is claimed hereby, and which is incorporated by reference herein in its entirety.

The present application is related to that of U.S. patent application Ser. No. 11/006,291, entitled APPARATUS AND METHOD FOR SUBCUTANEOUS ELECTRODE INSERTION, published as U.S. Published Patent Application No. 2006-0122676 on Jun. 8, 2006, now issued as U.S. Pat. No. 7,655,014, which is incorporated herein by reference.

FIELD

The present invention relates to the field of implantable cardiac stimulus device systems. More specifically, the present invention relates to insertion tools, lead assemblies, methods and kits for placement of cardiac device electrodes.

BACKGROUND

Implantable cardiac stimulus and/or monitoring devices and systems are known for use in ongoing and prophylactic treatment of cardiac conditions as well as diagnosis of cardiac maladies. Often such systems will include one or more lead assemblies that carry electrodes that may be used to sense cardiac activity and/or to deliver therapy to the patient. Convenient and uncomplicated, as well as quick, implantation of the lead assemblies is desirable, and alternatives to existing technologies and methods are sought.

SUMMARY

The present invention is, in several embodiments, directed toward insertion tools, lead assemblies, kits, and methods for placement of cardiac device electrodes. In some embodiments, an insertion tool having a proximal end and a distal, dissecting end includes a structure configured to receive or engage a structure on a lead assembly. Some embodiments include a lead assembly having an end including a structure configured for engaging the distal end of an associated insertion tool. Some embodiments include kits or systems including both an insertion tool and a lead assembly, each having a structure for engaging the other. In these embodiments, the engaging structures may take several forms including threads, small posts, circular or semi-circular receiving members, and/or a slot. Some embodiments also include methods for placement of cardiac device electrodes with the assistance of an associated insertion tool, wherein the cardiac device electrodes are associated with a lead assembly having an end configured to engage a distal, dissecting portion of an associated insertion tool.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an illustrative electrode insertion tool set;

FIGS. 2A-2E show steps of an illustrative method of implantation of a cardiac stimulus device;

2

FIGS. 3A and 3B are side views of an illustrative electrode insertion tool and an illustrative lead in detached and attached configurations;

FIGS. 4A and 4B are longitudinal cross-sectional views of another illustrative electrode insertion tool and an illustrative lead in detached and attached configurations;

FIGS. 4C-4E are views of alternative constructions along lines C-C, D-D and E-E of the illustrative electrode insertion tool and illustrative lead of FIG. 4A;

FIG. 4F is an illustrative cut-away view along line F-F of FIG. 4C;

FIG. 4G is an illustrative view along line G-G of FIG. 4E;

FIG. 5A is a side view of an illustrative electrode insertion tool and an illustrative lead in a detached configuration;

FIG. 5B is an axial elevation view of the distal end of the illustrative electrode insertion tool of FIG. 5A;

FIG. 5C is a side view of the illustrative electrode insertion tool and the illustrative lead of FIG. 5A in an attached configuration;

FIGS. 6A and 6B are side views of an illustrative electrode insertion tool and an illustrative lead in detached and attached configurations;

FIGS. 7A-7B are cross-sectional views of an illustrative electrode insertion tool and an illustrative lead assembly in detached and attached configurations to illustrate a locking mechanism;

FIG. 7C illustrates another locking mechanism;

FIG. 8A is a side view of another illustrative electrode insertion tool and an illustrative lead in a detached configuration;

FIG. 8B is a closer view of the distal tip of the illustrative lead in FIG. 8A; and

FIGS. 8C-8D are perspective views showing detached and attached configurations for the illustrative electrode insertion tool and illustrative lead of FIG. 8A.

DETAILED DESCRIPTION

The following detailed description should be read with reference to the drawings. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

As used herein, the proximal end of an electrode insertion tool is the end having a handle for grasping by the physician, and the distal end of an electrode insertion tool is the end having a dissecting tip for forming a path or opening through tissue and/or between layers of tissue. The proximal end of a lead electrode assembly is the end that is connected to an associated canister, while other end of a lead electrode assembly is referred to as the distal end.

FIG. 1 is a perspective view of an illustrative electrode insertion tool set. The illustrative set 10 includes several elements, including a straight introducer 12 having a handle 14, a shaft 16, and a distal tip 18. A curved introducer 20 is also shown, and includes a handle 22, a shaft 24, and a distal tip 26. A shaping tool 30 is also shown, the shaping tool having posts 32 disposed thereon. The shaping tool 30 may be used to adjust the curvature or shape of either of the introducers 12, 20. The handle of either or both introducers 12, 20 may include a port for fluid infusion, and the shafts 16, 24 or distal tips 18, 26 may include one or more ports allowing fluid (such as a local anesthetic, for example, lidocaine) to be infused during the insertion procedure. The distal tips 18, 26 may be shaped for blunt dissection including, for example, a relatively sharp distal tip portion forming a generally conical

dissection element. This allows for piercing and/or separation of tissue to form a space for insertion of a lead electrode assembly.

In an illustrative embodiment, a straight electrode insertion tool has an overall length, including the handle, of about 26.5 cm, with the shaft having an outer diameter of about 3.2 millimeters. Other embodiments may range from about 1 mm to about 6 mm in outer shaft diameter, with an overall length between about 10 cm and about 40 cm. An illustrative shaft is formed of stainless steel, with a polycarbonate proximal handle. Alternatively, a polymer providing added shapeability may be used for the shaft. A polytetrafluoroethylene coating may be used, if desired. Other coatings may be used, including drug eluting coatings. The overall size may be modified in light of patient anatomy, desired implant location, and the size of the lead electrode assembly being used, for example.

FIGS. 2A-2E show steps of an illustrative method of implantation of a cardiac stimulus device and lead assembly to a subcutaneous location. Beginning with FIG. 2A, a patient 40 is shown having a heart generally at 42, with the median or sagittal plane shown generally at 44. At a location about 0 cm to about 4 cm superior or inferior to the xiphoid process 46, a first incision 48 is made at a medial location. In an illustrative embodiment, the first incision 48 is about 1 cm to about 2 cm inferior to the xiphoid process. A subcutaneous pocket 50 may be formed in a suitable fashion for receiving the canister of the cardiac stimulus device, with the subcutaneous pocket 50 formed near a second incision 52. An electrode insertion tool is shown, with shaft 54 and handle 56, and, as indicated by the arrow, is inserted through the first incision 48 and advanced toward the second incision 52, creating a channel through the patient's subcutaneous tissue.

Turning to FIG. 2B, the insertion tool is advanced through first incision 48 toward the second incision 52 through subcutaneous tissue until the distal end 58 exits the second incision 52, such that the shaft 54 temporarily resides in the subcutaneous tissue of the patient. Next, a lead assembly 60 is provided, with a distal end 62 and a proximal end 64. The proximal end of the lead assembly 60 is shown including a plug or connector for attachment to an associated canister. The distal end 62 of the lead assembly 60 is secured to the distal end 58 of the electrode insertion tool. The physician then grasps the handle 56 and, as indicated by the arrow, withdraws the electrode insertion tool via the first incision 48, pulling the lead assembly 60 into the subcutaneous space or channel previously dissected.

Referring now to FIG. 2C, the result of the steps shown in FIG. 2B is that the lead assembly 60 now resides partly in the patient's subcutaneous tissue, with the proximal end with plug or connector 64 sitting outside of the patient near the second incision 52, and the distal end 62 extending out of first incision 48. As indicated in FIG. 2C, the next step is for the insertion tool to be inserted through a third incision 70 and advanced toward and through the first incision 48. The third incision 70 may be approximately 8-10 cm (or more or less, depending on patient anatomy) above the first incision 48, to the left of the median or sagittal plane 44, and cephalad of the first incision 48. The first and second incisions may be placed such that a line drawn therebetween is parallel to the patient's sternal midline, with the incisions being spaced about 0 cm to about 5 cm to the left of the sternal midline. In the embodiment shown, a parasternal implant location is achieved by placing the incisions about 3 cm to the left of the sternal midline. The insertion tool is advanced toward the first incision 48 until the distal end 58 of the insertion tool exits the first incision 48.

Turning to FIG. 2D, the lead assembly 60 is manipulated such that its distal end 62 is adjacent the distal end 58 of the insertion tool. The distal end 62 of the lead assembly 60 is then secured to the distal end 58 of the insertion tool. An implanting physician then grasps the handle 56 and withdraws the insertion tool as indicated by the arrow, pulling the distal end 62 of the lead assembly 60 toward the third incision 70.

FIG. 2E illustrates the completed procedure. The lead assembly 60 is disposed in a subcutaneous space in a generally "L" shape. The distal end 62 of the lead assembly 60 is disposed near the third incision, which is shown as a closed incision 70'. As shown by the insets, the distal end 62 of the lead assembly 60 may be secured, using suture hole 66, to the fascia near the third incision by sutures 68. Likewise, a medial portion of the lead assembly 60 may be secured to fascia near the first incision (shown as closed incision 48') using suture(s) 86 that are secured to a suture sleeve 84 that may be secured to the lead assembly 60. The addition of these sutures 68, 86 is optional, but may aid in acute retention of the position of implantation. As time passes, tissue surrounding the electrode and/or lead assembly will fibrose and also hold the lead assembly in place. For example, the sutures 68, 86 may be formed of biocompatible, dissolvable material.

FIG. 2E also illustrates placement of the canister 78 relative to the rest of the implanted system. In particular, the canister 78 is placed near the second incision (shown as closed incision 52') in the subcutaneous pocket 50 (FIG. 2A). The lead assembly 60 is secured to the canister 78, and extends first medially toward the first incision (shown as closed incision 48') and then cephalad toward the third incision (shown as closed incision 70').

A distal portion of the lead assembly 60 is shown as including a plurality of electrodes, as shown at 80. The number and type of electrode(s) may vary, with at least one electrode included. In an illustrative embodiment, the electrodes 80 include a distal ring electrode used primarily for sensing, a proximal ring electrode also used primarily for sensing, and a coil electrode therebetween, with the coil electrode used for delivering stimulus, although each electrode may perform more than one function. The canister 78 may also include one or more electrodes. The lead assembly 60 further includes a proximally extending shaft having conductors passing there-through, with the shaft providing insulation to the conductors, and with the conductor(s) coupled to the one or more electrodes.

Alternatives to the steps shown in FIGS. 2A-2E are available in other embodiments. In some embodiments, the first incision 48 and/or third incision 70 may be at different locations, for example, to the right of the median or sagittal plane, or, rather than at an anterior position as shown, posterior to the patient. Further, the pocket 50 for receiving the canister of the system may be moved to a more cephalad position (for example, near the clavicle). The canister 78 is shown as generally rectangular, although other shapes, including a long, narrow shape that conforms to the patient's ribcage, may instead be used.

Part of the implantation procedure shown in FIGS. 2A-2E includes steps in which an electrode insertion tool is used to first create a subcutaneous pathway, is then connected at its distal end to a lead assembly, and is then used to pull the lead assembly through the just created subcutaneous pathway. When the desired configuration has an "L" shape as shown by FIG. 2E, these steps may be performed twice, such that either one electrode insertion tool is coupled to, de-coupled from, re-coupled to, and re-de-coupled from the lead assembly, or first and second electrode insertion tools are successively

5

coupled to and decoupled from the lead assembly. In either event, it is desired to have the ability to readily and easily couple the lead assembly to the electrode insertion tool to perform the step of pulling the lead assembly through the patient's subcutaneous tissue to a desired location. Following are several illustrative examples that provide such functionality.

It may also be noted that the implantation procedure in FIGS. 2A-2E does not require the use of a splittable sheath. Additional structures, such as a sheath or a splittable sheath may be added, if desired, but the procedure does not require such elements. The method thus includes establishing a subcutaneous pathway by the use of an implantation tool, securing a lead assembly for use in the cardiac device system to the implantation tool, and pulling the lead assembly into the subcutaneous pathway, wherein the lead assembly is pulled into the subcutaneous pathway in its finished condition, without the use of a sheath or splittable sheath thereon.

FIG. 3A is a side view of an illustrative electrode insertion tool **100** and an illustrative lead assembly **102** in a detached configuration. FIG. 3A generally shows the distal ends of each of the illustrative electrode insertion tool **100** and the illustrative lead assembly **102**. The electrode insertion tool **100** includes a dissecting tip **104**, which is shown as a generally sharp member. Proximal and adjacent to the dissecting tip **104** is a lead engaging structure **106** that is configured for engaging the lead assembly **102**. Further proximal on the electrode insertion tool **100** is a dissecting portion **108** that is shaped to further expand and dissect subcutaneous space as the electrode insertion tool **100** is advanced through subcutaneous tissue.

The lead assembly **102** also includes an engagement structure **110** that is configured to engage and secure to the tool **100**. In the illustrative embodiment, the engagement structures **106**, **110** take the form of cooperating threading that allows for rotational fixation of the lead assembly **102** to the introducer **100**. The lead assembly **102** defines, at its distal end, a cavity wall **112** shaped to receive the dissecting tip **104** therein. As such, the lead assembly **102** includes a receiving structure including both the engagement structure **110** and the cavity/cavity wall **112**. Also shown on the lead assembly **102** is a suture hole **116**, which may be used, as illustrated in FIG. 2E, to provide an acute or chronic retention structure.

The electrode insertion tool **100** is shown as including a proximally facing shoulder **114**. This shoulder **114** may be abrupt, as shown, or may be smoothed or curved in to avoid catching on and/or tearing subcutaneous tissue as the electrode insertion tool **100** is manipulated in a proximal direction. The outer diameter of the dissecting portion **108** and/or proximally facing shoulder **114**, in some embodiments, may be sized to be greater than the outer diameter of the lead assembly **102** such that, as the lead assembly **102** is pulled through subcutaneous tissue, drag on the lead assembly **102** is reduced to avoid damage during the pulling step. For example, the outer diameter of the dissecting portion **108** may be about 0.3 mm to about 5.0 mm larger than the outer diameter of a corresponding lead assembly **102** to reduce drag. In other embodiments, the outer diameter for the electrode insertion tool **100** is generally similar to the outer diameter of the lead assembly **102**, which may reduce the level of patient discomfort during the procedure.

FIG. 3B is a side view of the electrode insertion tool and the lead of FIG. 3A in an attached configuration. As can be seen at **118**, the electrode insertion tool **100** is secured to the lead assembly **102**, with the cooperative threading of the engaging structures removably fixing the two pieces **100**, **102** together. The cavity wall **112** is formed such that the dissecting tip **104**

6

is easily received in the distal end of the lead assembly **102** while the electrode insertion tool **100** is attached to the lead assembly **102**. Once the lead assembly **102** is drawn through a subcutaneous path and the distal end of the lead assembly **102** is at its desired location, the suture hole **116** may be used to secure the lead assembly in place. In the illustrative embodiment, the direct attachment of the lead assembly **102** to the electrode insertion tool **100** allows for a simple and quick implantation procedure.

FIG. 4A is a longitudinal cross-sectional view of another illustrative electrode insertion tool **200** and an illustrative lead assembly **202** in a detached configuration. The electrode insertion tool **200** includes a dissecting tip **204**, an engaging structure **206**, and a dissecting portion **208**. As before, the dissecting tip **204** may be sharp or blunt, and the dissecting portion **208** is sized to further expand a subcutaneous channel formed as the electrode insertion tool **200** is advanced through tissue.

In the embodiment of FIG. 4A, an internal channel **210** is also illustrated. The internal channel **210** may be used to infuse a fluid during the implantation procedure, for example, a local anesthetic, anti-inflammatory drugs, antibiotics, visualization media or any other suitable material, as desired. The channel **210** is shown with openings at various locations, including on the dissecting portion **208** as well as the more proximal shaft region of the electrode insertion tool **200**. These openings may be placed as desired. In addition, an opening may be placed at or near the dissecting tip **204**.

The embodiment of FIG. 4A also illustrates the illustrative lead assembly **202** as including an engaging structure **212**, which generally includes a ridge **214**, and a cavity **216**. The cavity **216** and engaging structure **212** provide a receiving location for a distal portion of the electrode insertion tool **200** such that the ridge **214** secures the lead to the tool **200**. The lead assembly **202** may also include a suture hole as shown at **218**. As indicated by the alternate view lines, FIGS. 4C, 4D and 4E illustrate various forms for the engaging structures, and are further explained below. These structures may include select twist-locking structures and/or a slide-over or snap-fit structure, as further explained below.

FIG. 4B is a longitudinal cross-sectional view of the electrode insertion tool and the illustrative lead of FIG. 4A in an attached configuration. When in the attached configuration, the dissecting tip **204** of the electrode insertion tool **200** is disposed in the cavity **216** of the lead assembly **202**, with the tool engaging structure **212** of the lead assembly coupled to the lead engaging structure **206** of the electrode insertion tool **200**.

FIGS. 4C-4E are elevation views of constructions along lines C-C, D-D and E-E of the illustrative electrode insertion tool **200** and illustrative lead assembly **202** of FIG. 4A. Referring to FIG. 4C, the electrode insertion tool **200** is shown as including the dissecting tip **204**, lead engaging structure **206**, and dissecting portion **208**. The lead engaging structure **206** is shown generally at **230** as including a pair of tabs. The lead assembly **202** is shown as including a ridge **214** about cavity **216**. The ridge **214** is shown generally as a disc that extends inward from an outer sheath into the chamber **216**, the disc including a pair of gaps **232** that are spaced and sized to receive the tabs **230** of the lead engaging structure **206**. Turning to FIG. 4F, it can be seen that the disc provides a ledge **234** for holding tabs **230**. The tool engaging structure is shown in FIG. 4F as including a ramp **236** that leads up to a slot **238**. When the tabs **230** are passed through the gaps **232** and the

7

electrode insertion tool **200** is twisted relative to the lead assembly **202**, at least one of the tabs passes over the ramp **236** until it crosses the end of the ramp **236** and settles into the slot **238**. Maintaining even slight axial tension can help to hold the tabs **230** in the slot **238** as the electrode insertion tool is pulled from its proximal end.

Referring now to FIG. 4D, a slide-over or snap-fit structure is illustrated. In particular, the illustrative electrode insertion tool **200** includes an engaging structure **206'** including an annular disc **240**. The annular disc **240** projects out from the surface of the engaging structure, but with a lesser diameter than the outer diameter of the dissecting portion **208**. The lead assembly **202** includes a chamber **216** and a ridge **214'** which is also a disc **242** structure, this time projecting inward from the outer wall of the chamber **216**. One, the other, or both of the discs **240**, **242** may be flexible to allow the discs to be passed over one another.

Referring now to FIG. 4E, another construction is shown, this time with the electrode insertion tool **200** including an engagement structure **206''** having a disc defining gaps **250**. Again, the engagement structure **206''** sits proximal of the dissecting tip **204** and distal of the dissecting portion **208**. The lead assembly **202** includes a ridge **214''** and a chamber **216**, with the ridge **214''** reduced to tabs **252** sized to fit through the gaps **250** of the electrode insertion tool **200**. FIG. 4G shows the structure of the electrode insertion tool from line G-G. As can be seen, the engaging structure **206''** on the electrode insertion tool **200** again includes the gap **250** and defines a channel for sliding the tabs **252** up a ramp **254** to a receiving slot **256**. Again, a certain amount of axial tension may help to retain the tab(s) **252** in the slot **256**.

In FIGS. 4C and 4E, the number and shape of the tabs **230**, **252** may vary, and the particulars described in each structure are merely illustrative of some embodiments.

FIG. 5A is a side view of an illustrative electrode insertion tool **300** and an illustrative lead assembly **302** in a detached configuration. The electrode insertion tool **300** again includes a dissecting tip **304**, an engaging structure **306**, and a dissecting portion **308** which may be included to further dissect tissue. The engaging structure includes a slot **310** that is adapted to receive a corresponding engaging structure **320** on the lead assembly **302**. Openings **312** are also shown and communicate with the slot **310**, allowing a suture to pass therethrough.

The lead assembly **302** includes, as indicated, an engaging structure **320**, which is shown as including a suture hole. The lead assembly **302**, as with each lead assembly shown herein, may include any suitable number, configuration, and type of electrodes. One suitable configuration is shown in FIG. 5A as including a distal ring electrode **322** and a proximal ring electrode **326**, with a coil electrode **324** therebetween. Other configurations may also be used, as suits the particular system, application, and patient. The lead assembly **302** includes an engaging structure **320** that extends therefrom. As explained below by reference to FIG. 5C, the engaging structure **320** of the lead assembly **302** is sized and shaped for placement in the slot **310** of the electrode insertion tool **300**. Also, the engaging structure **320** of the lead assembly **302** is shown with a suture hole that may be used both in securing the lead assembly to the electrode insertion tool, and also for suturing to tissue after placement.

FIG. 5B is an axial elevation view of the distal end of the illustrative electrode insertion tool of FIG. 5A. The electrode insertion tool **300** includes the dissecting tip **304** and the

8

engaging structure **306**. The dissecting portion **308** is omitted, as it may be omitted in some embodiments not only of the electrode insertion tool **300** in FIGS. 5A-5C, but also in the other embodiments shown herein. The engaging structure **306** includes slot **310** and openings **312** that communicate with the slot **310**.

FIG. 5C is a side view of the illustrative electrode insertion tool and the illustrative lead of FIG. 5A in an attached configuration. As can be seen, the engaging structure **320** of the lead assembly **302** is inserted into the slot **310**. A suture **330** passes through the openings **312** to the suture hole on the engaging structure **320** of the lead assembly **302** while it rests in the slot **310**. As such, the suture **330** secures the lead assembly **302** to the electrode insertion tool **300**. If desired, the engaging structure **320** of the lead assembly **302** may be shaped or marked to aid in correct alignment of the suture hole of the engaging structure **320** with the openings **312** and the slot **310**. For example, the engaging structure **320** of the lead assembly may be oblong or polygonal.

In the embodiment of FIGS. 5A-5C, the electrode insertion tool **300** includes a receiving portion for receiving the engaging structure **320** of the lead assembly **302**. The receiving portion includes the engaging structure **306** at the distal end of the electrode insertion tool.

FIG. 6A is a side view of an illustrative electrode insertion tool **400** and an illustrative lead assembly **402** in a detached configuration. The electrode insertion tool **400** includes a dissecting tip **404**, an engaging structure **406** and a dissecting portion **416**. The example lead assembly **402** includes an engaging structure **420** including a suture hole **422**, as well as a configuration of multiple electrodes **424**, **426**, **428**.

The illustrative engaging structure **406** includes a hook **408**, elongate shaft **410**, and actuator **412**, with the actuator **412** shown as being associated with the device handle **414**. The hook **408** is shown in a retracted position such that its distal end exits and then reenters the lead assembly **402**. The actuator **412** is coupled to the elongate shaft **410** to control whether the hook **408** is in the retracted position shown in FIG. 6A or the extended position shown in FIG. 6B.

FIG. 6B is a side view of the illustrative electrode insertion tool and the illustrative lead of FIG. 6A in an attached configuration. The actuator **412** on the device handle **414** has been manipulated, such that the hook **408** extends from the distal end of the electrode insertion tool **400** and away from the reentry opening **418**. The hook **408** has been placed into the suture hole **422** on the engaging structure **420** of the lead assembly **402**. Thus, the engaging structure **406** of the electrode insertion tool **400** interacts with the engaging structure **420** of the lead assembly **402** to secure the two together. In some embodiments, a slot may be provided on the electrode insertion tool **400** to receive the engaging structure **420** of the lead assembly as well, for example, in a manner as shown in FIGS. 5A-5C.

FIGS. 7A-7C show an illustrative embodiment in which a locking structure is provided in addition to the engaging structures. Referring to FIG. 7A, an electrode insertion tool **500** is shown detached from an illustrative lead assembly **502**. The electrode insertion tool **500** includes a dissecting tip **504**, and engaging structure **506** (shown as threading), and a dissecting portion **508**. A locking structure **510** is also shown.

The lead assembly **502** includes an engaging structure **512** for threading onto the engaging structure **506** of the electrode insertion tool **500**. The receiving chamber **514** is configured to receive the distal end of the electrode insertion tool **500**. A locking structure **516** is also shown, and is further explained by reference to FIG. 7B.

Referring to FIG. 7B, the engaging structures **506**, **512** of the electrode insertion tool **500** and lead assembly **502** are shown in a secured configuration. The locking structure **510** of the electrode insertion tool **500** is shown as including a locking key **520**. When advanced as shown, the locking key **520** engages the locking structure **516** of the lead assembly **502**, preventing the lead assembly **502** from becoming unthreaded from the electrode insertion tool **500**.

FIG. 7C shows another embodiment, including the actuator **542** for the locking key **520**. In particular, the actuator **542** may be part of the device handle **540**. The locking key **520** may be coupled to the actuator **542** by an elongate shaft extending through the length of the electrode insertion tool **500**. The embodiment of FIG. 7C shows an alternative to the locking structure **516** of FIGS. 7A-7B. In particular, rather than a small location that may receive the locking key **520**, the lead assembly **502'** may include a fin **532** that prevents full rotation of the lead assembly **502'** relative to the electrode insertion tool **500** when the locking key **520** is disposed in the receiving chamber **530**. Several fins **532** may be provided, or a solid member may be provided to take up a portion of the space in the receiving chamber **530** to prevent rotation of the lead assembly **502'** relative to the electrode insertion tool **500**.

FIGS. 7A-7C also illustrate an electrode insertion tool **500** which includes a distal enlargement for dissecting patient tissue that has a distally facing dissecting portion **508** as well as a proximally facing, non-abrupt shoulder **550**. As discussed above, the proximally facing shoulder **550** may be formed to allow smooth passage through the already dissected subcutaneous tissue, while also creating a pathway for drawing the lead assembly **502**, **502'** easily therethrough. A smooth shoulder may be provided in any suitable fashion, for example, by smoothing the outer edge of the shoulder down, or by providing an angled shoulder, as is shown in FIGS. 7A-7C.

FIG. 8A is a side view of another illustrative electrode insertion tool **600** and an illustrative lead assembly **602** in a detached configuration. The electrode insertion tool **600** includes a receiving portion **604** located proximal of a dissecting tip, with an additional dissecting portion extending proximally of the receiving portion **604**. The receiving portion **604** includes a channel **606** and a slot **608**, with the channel **606** and the slot **608** shown in phantom to illustrate that they are not open to the outer surface of the electrode insertion tool **600**. The illustrative lead assembly **602** includes electrodes **610** and an attachment structure **612** including a tab **614**.

FIG. 8B is a closer view of the distal tip of the illustrative lead in FIG. 8A. The attachment structure **612** extends axially from the distal end of the lead assembly **602** (FIG. 8A). A tab **614** extends laterally from the distal end of the attachment structure **612**. The attachment structure **612** and tab **614** are configured to cooperate with the receiving portion **604**, channel **606** and slot **608** shown in FIG. 8A, as is further shown in FIGS. 8C-8D.

FIGS. 8C-8D are perspective views showing detached and attached configurations for the illustrative electrode insertion tool and illustrative lead of FIG. 8A. The attachment structure **612** is aligned such that the tab **614** aligns with the receiving portion **604**. As indicated by arrow **630**, the attachment structure **612** is inserted in the receiving portion **604** until the tab **614** is inside the receiving portion and aligns with the channel **606**. As indicated by line **632**, the attachment structure **612** and lead assembly are then rotated relative to the insertion tool **600** (or vice versa), such that the tab **614** slides through the channel **632**.

In the illustrative embodiment of FIGS. 8A-8D, the slot **608** is included. The slot **608** is optional, and may be omitted if desired. As indicated by line **634**, once the tab **614** slides through the channel **606** to a position in alignment with the slot **608**, the lead assembly and insertion tool **600** are moved axially relative to one another such that the tab **614** enters the (optional) slot **608**.

FIG. 8D shows the lead assembly secured to the insertion tool **600**, with the attachment structure **812** engaged with the slot **608** after passing the tab **614** through the receiving portion **604** and channel **606**. While in this configuration, the insertion tool **600** is drawn out through the subcutaneous path it established prior to being connected to the lead assembly. Once the insertion tool **600** has been withdrawn, the engaging structure **612** is disengaged by maneuvering the tab **614** out of the slot **608**, into the channel **606**, and around to the receiving structure **604**.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. A tool for use in subcutaneous insertion of a lead electrode assembly, the tool comprising:

a proximal end having a handle;
a distal end including a dissecting tip shaped for separating subcutaneous tissue to form a channel therethrough, and an engaging structure disposed adjacent to the dissecting tip; and

a shaft extending between the proximal and distal ends; wherein the engaging structure is configured to directly engage a portion of an associated lead assembly;

further wherein:

the distal end further comprises a dissecting portion proximal to the engaging structure, the dissecting portion shaped to further separate subcutaneous tissue relative to the dissecting tip such that, when the engaging structure is used to secure the lead electrode assembly thereto, and the handle is pulled in a proximal direction, the dissecting portion reduces drag on the lead assembly;

the dissecting tip, engaging structure, and dissecting portion generally form a conical portion with a discontinuity at the engaging structure, the discontinuity extending at least partly about the conical portion; and wherein the engaging structure includes a transversely extending structure.

2. The tool of claim 1, wherein the discontinuity extends wholly around the conical portion.

3. The tool of claim 1, wherein the transversely extending structure forms a ridge and a slot.

4. The tool of claim 1, further comprising means for locking the tool in an engaged configuration relative to a lead assembly configured to engage the engaging structure of the tool.

5. The tool of claim 1, further comprising a locking member coupled to a control mechanism disposed relative to the handle, the locking member configured to lock the tool in an engaged position in response to actuation by the control mechanism.

6. The tool of claim 1, further comprising a locking member coupled to means for controlling the locking member, the means for controlling the locking member accessible at or near the handle, the locking member configured to lock the tool in an engaged configuration relative to a lead assembly when actuated by the means for controlling.

11

7. The tool of claim 1, wherein a shoulder is defined between the distal end and the shaft proximally adjacent the distal end, wherein the shoulder is shaped for non-traumatic passage in a proximal direction through subcutaneous tissue.

8. A lead assembly for a cardiac stimulus system, the lead assembly comprising:

a distal end comprising at least a first electrode and a distal tip; and

a proximally extending shaft including an electrical conductor coupled to the first electrode;

wherein the distal end further comprises an engagement structure configured for direct engagement with an associated introducer tool and a receiving portion for receiving the distal end of the associated introducer tool such that, when an associated introducer tool is received in the receiving portion, the distal tip of the lead assembly extends over and around a portion of the associated introducer tool;

wherein the engagement structure includes one or more tabs extending into the receiving portion from an outer sheath near the distal tip.

12

9. A lead assembly for a cardiac stimulus system, the lead assembly comprising:

a distal end comprising at least a first electrode and a distal tip; and

a proximally extending shaft including an electrical conductor coupled to the first electrode;

wherein the distal end further comprises an engagement structure configured for direct engagement with an associated introducer tool and a receiving portion for receiving the distal end of the associated introducer tool such that, when an associated introducer tool is received in the receiving portion, the distal tip of the lead assembly extends over and around a portion of the associated introducer tool;

wherein the engagement structure includes one or more slots adjacent a disk, the slots sized and configured to receive corresponding tabs on the associated introducer tool.

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